510(k) Summary

JUN 0 7 2013

Date Prepared:	March 28, 2013
Contact:	Jessee Hunt, President 4Web, Inc. 6170 Research Rd. Suite 219 Frisco, TX 75033 Phone: (800) 285-7090 Fax: 972-488-1816
Trade Name:	4Web Osteotomy Bone Wedge
Product Class:	Class II
Classification:	21 CFR §888.3030 Single/multiple component metallic bone fixation appliances and accessories
Common Name:	Bone Wedge
Product Codes:	HRS
Panel Code:	87

Indications for Use:
The 4Web Osteotomy Bone Wedge is intended to be used for internal bone fixation or osteotomies in the foot, such as:

1. Opening wedge osteotomies of Hallux Valgus
2. Cotton opening wedge osteotomies
3. Evans lengthening osteotomies

These devices are intended to be used with autograft bone and ancillary fixation.
The 4Web Osteotomy Bone Wedge is not intended for use in the spine.

Device Description:
The 4Web Osteotomy Bone Wedge is a titanium alloy implant used for correction of small bones in the foot. It is offered in two shapes and multiple sizes for each shape with varying widths and thicknesses to accommodate a variety of small bone applications. Each device uses the 4-Web truss system of architecture. Implants are made from medical grade titanium allow (6Al4V-ELI) per ASTM F-136/ISO 5832-3.

Predicate Device(s):
The 4Web Osteotomy Bone Wedge is substantially equivalent to the Biofoam Bone Wedge from Wright Medical (K073535).

Performance Standards:
The pre-clinical testing performed includes static and dynamic compression testing per ASTM F2077-11 and expulsion testing. The results indicate that the 4Web Osteotomy Bone Wedge is substantially equivalent to the predicate device and is adequate for the intended use.

Conclusion:
4Web, Inc concludes that these osteotomy bone wedges are substantially equivalent to the osteotomy bone wedges from Wright Medical and raise no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 7, 2013

4Web, Incorporated
% Silver Pine Consulting, LLC.
Richard Jansen, Pharm. D.
Consultant
13540 Guild Avenue
Apple Valley, Minnesota 55124

Re: K130185
Trade/Device Name: 4Web Osteotomy Bone Wedge
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: March 28, 2013
Received: April 1, 2013

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Indications for Use

510(k) Number: K130185

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Prescription Use ___V____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices